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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/790,033	03/02/2004	James Wilson-MacDonald	1011-001-10316	9744

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PAUL J. SUTTON, ESQ., BARRY G. MAGIDOFF, ESQ.
GREENBERG TRAURIG, LLP
200 PARK AVENUE
NEW YORK, NY 10166

EXAMINER

SHAFFER, RICHARD R

ART UNIT PAPER NUMBER

3733

DATE MAILED: 10/31/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/790,033	WILSON-MACDONALD ET AL.	
	Examiner	Art Unit	
	Richard R. Shaffer	3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 August 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-8,10-12,14,15 and 17-29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-8,10-12,14,15 and 17-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 02 March 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input checked="" type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date: _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date: _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Allowable Subject Matter

The indicated allowability of previous claim 16 is withdrawn after additional consideration of the previously applied reference to Martin (US Patent 5,672,175). The rejections based on the new interpretation(s) follow.

Information Disclosure Statement

The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Drawings

The drawings are objected to because they are of poor quality in regard to the structure of the components of the device as well as failing to meet formal requirements according to the attached Draftsperson's Drawing Review. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary,

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the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

The amendments to the specification filed on August 23rd, 2006 are acknowledged and accepted by the examiner.

The abstract of the disclosure is objected to because of undue length. An abstract must be a concise (50 to 150 words) summary of the novelty of the invention. Correction is required. See MPEP § 608.01(b).

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. The current title does not provide a reader knowledge of the dynamic spinal correctional forces employed.

The disclosure is objected to because of the following informalities:

- Summary of Invention, Page 4: The specification references claims 2-24 to describe the device. This is improper. The specification must be able to stand-alone from the claims.

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- Brief Description of Drawings: Figures 2 and 3 refer to "embodiments."

Clearly, they only show additional view of a single embodiment.

Appropriate correction is required.

While the amendment to the specification filed on August 23rd, 2006 corrected for improper multiple dependency and providing antecedent basis for a mobile device, applicant still has failed to provide for antecedent basis in the specification for language utilized in the claims such as "connecting means," "releasable clamping means," and "unidirectional gripping means." Due to the lack of antecedent basis in the claims, they cause one of ordinary skill in the art confusion in determining what the claim encompasses. The specification is therefore objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction is required:

Claim Rejections - 35 USC § 112

The amendment to claims filed on August 23rd, 2006 are acknowledged and accepted by the examiner. They correct for the previous rejection under 35 U.S.C. 112, second paragraph.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 3-8, 10-12, 14, 15, and 17-25 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable

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one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Independent claims 1 and 20 recite the limitation "wherein said tension or compression is achieved through pushing or pulling said spring through said unidirectional gripping means." The device as understood uses an enlarged clamp (12) that is fixed to the spring (4) and merely abuts against the ring (11) to stop further translation of the spring with respect to the plate (5) it is not locked. Clearly then, unless the clamp was moved to the opposite side of the ring, it would not be capable of limiting translation through the non-locked connection in one of the two modes. As shown in **Figure 1**, the clamp (12) is clamp is maintaining a tensile force by abutting the ring (11) and not allowing the spring (4) to collapse. If the spring was in compression and wanted to expand, the current positioning of the clamp to ring would merely push the clamp away resulting in no loading across the vertebral space. Therefore, claims 1 and 20 are claiming a device to which applicant has not disclosed capable of performing said claimed function.

All dependent claims to claims 1 and 20 are rejected for being dependent upon a non-enabled base claim.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 3-8, 10-12, 14, 15, and 17-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Independent claims 1 and 20 recite the limitation "at least one of said first and second attachment means comprises unidirectional gripping means which allow motion of said spring in relation **to said attachment means**." The last portion reciting "to said attachment means" is indefinite because motion of the spring is only in relation to one of the attachment means due to one end being locked to the spring while the other attachment means allows sliding. It is recommended applicant uses language such as "... which allow motion of said spring in relation to said at least one of said attachment means."

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1, 3-8, 10-12, 14, 15, and 17-29 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Independent claims 1, 20, 26 and 28 recite the limitation "said unidirectional force is applied by said [spring or unidirectional force generating means] via said first and second attachment means to said first and second vertebrae." Applicant needs to add language clearly stating that the force is capable of being applied to the vertebrae and not merely is applied avoiding positively reciting the human body.

Independent claims 1, 20, 26 and 28 also recite the limitation "whereby, over said period of time, said unidirectional force urges a proprioceptively neutral position of said first and second vertebrae." Again, applicant needs to add capable/adapted/for language to clearly state that a portion of the human body is not being positively recited.

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All dependent claims have been rejected for being depended upon a non-statutory base claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 4-8, 10, 11, 14, 15, 17 and 20-29 are rejected under 35 U.S.C. 102(b) as being anticipated by Martin (US Patent 5,672,175).

Martin discloses a device (**Figures 1-12**) comprising: a plurality biocompatible, shape memory; metal (**Column 6, Lines 29-36 and Column 8, Line 64**) springs (**21a/b-24a/b**) for generating a unidirectional force (magnitude determined pre- or intra-operation: **Column 4, Lines 36-41**) in either tension or compression (**Column 5, Lines 62-65**); the springs (**21a/b-24a/b**) being coiled (**Column 5, Line 55 through Column 6, Line 13**), leaf or other springs (**Column 20, Lines 4-5**); a first attachment means (**1**); second attachment means (**3**); a spring (**21a/b-24a/b**) placed between the attachment means (**1 and 3**); at least one of the attachment means including a base plate (**55, 55a**) and connecting means (**29 and 10**) which connects a free end (**27**) of a spring (**21a/b-24a/b**) to the base plate (**55, 55a**); the connecting means (**29 and 10**) having two locations for attaching to the base plate (above and below in relation to the spine being vertically orientated) either singly or in pairs; a mobile joint (**sphere 8 with spherical housing 9 in cylinder 10; Column 9, Lines 37-42**); a gripping means (**35**) that will

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allow motion of the spring in one axial direction and not the other in relation to an attachment means; and clamping means (29, 30, 31; Column 12, Lines 29-50) with a screw (32) to clamp and release.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 3, 12, 18 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Martin.

Martin discloses all of the claimed limitations except is silent as to the upper unidirectional force being 200 N (the low end of 0 N is inherent to the nature of the device) and the spring being designed into the shape of a C or S.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the springs of Martin within the range of 0-200 N since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

It would have been further a matter of obvious design choice to one skilled in the art at the time the invention was made to construct the springs of Martin in a C or S-shape, since applicant has not disclosed that such a shape solves any stated problem or is anything more than one of numerous shapes or configurations a person of ordinary

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skill in the art would find obvious for the purposes of providing a compression or extension force. *In re Dailey and Eilers*, 149 USPQ 47 (1966).

Response to Arguments

Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

This action is **NOT** Final due to the new grounds of rejection not necessitated by the amendment filed on August 23rd, 2006.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Richard R. Shaffer whose telephone number is 571-272-8683. The examiner can normally be reached on Monday-Friday (7am-5pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Richard Shaffer
October 25th, 2006



EDUARDO C. ROBERT
SUPERVISORY PATENT EXAMINER